

Dockets Management Branch  
The Food and Drug Administration  
Department of Health & Human Services, Rm. 1-23  
12420 Parklawn Dr.  
Rockville, MD 20857

Date: 10/27/99

Re: 99P-1340/CP 1 — Petition to Have *Eternity* eau de parfum declared "Misbranded"

2562 99 OCT 29 P136

Dear Sir or Madam:

In May 1999, the Environmental Health Network (EHN) submitted the above petition to have Calvin Klein's *Eternity* eau de parfum declared "misbranded." I am writing because I fully support this petition and request that the FDA give it careful attention with regard to your regulations 21CFR Sec. 740.1, 21CFR Sec. 740.2, and 21CFR Sec. 740.10. Regulation 21CFR Sec. 740.10 states:

Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel:

"Warning — The safety of this product has not been determined."

As the petition shows, *Eternity* contains toxic ingredients and ingredients whose safety have not been substantiated. There is no warning label on its packaging.

We all have a right to know the status of safety testing of the ingredients in products such as *Eternity* so that we can protect ourselves and our families from toxic chemicals that may cause health problems. Most people are not aware that most fragrance materials have only limited safety testing. They wrongfully assume these products are safe to use in any setting and are surprised when people complain.

Like tobacco smoke, the harmful chemicals currently used in these products may affect the health of many people, including: people with asthma, chemical sensitivities, chronic fatigue, and other environmental illnesses. Children are particularly vulnerable to toxic chemicals found in products purchased and used by their parents, caregivers and teachers. When I am exposed to fragrance products I can experience any of the following symptoms based upon the chemical fragrance product I encounter:

- |  |   |  |  |
|--|---|--|--|
| <input type="checkbox"/> anaphylaxis/shock               | <input type="checkbox"/> double vision                      | <input type="checkbox"/> incoherence                 | <input type="checkbox"/> nausea                |
| <input type="checkbox"/> anxiety, restlessness           | <input type="checkbox"/> ear pain                           | <input type="checkbox"/> incontinence                | <input type="checkbox"/> nose bleeds           |
| <input checked="" type="checkbox"/> asthma               | <input type="checkbox"/> eczema                             | <input type="checkbox"/> irritability                | <input type="checkbox"/> rashes                |
| <input checked="" type="checkbox"/> breathing difficulty | <input checked="" type="checkbox"/> eyes, watery or dry     | <input type="checkbox"/> joint aches                 | <input type="checkbox"/> seizures              |
| <input type="checkbox"/> bronchitis                      | <input type="checkbox"/> fatigue                            | <input type="checkbox"/> laryngitis                  | <input type="checkbox"/> short-term mem. loss  |
| <input checked="" type="checkbox"/> can't concentrate    | <input type="checkbox"/> flushing                           | <input type="checkbox"/> lethargy                    | <input type="checkbox"/> sinusitis             |
| <input type="checkbox"/> coughing                        | <input checked="" type="checkbox"/> headaches               | <input type="checkbox"/> lymph nodes swell           | <input type="checkbox"/> sneezing              |
| <input type="checkbox"/> depression                      | <input checked="" type="checkbox"/> heart beat irregularity | <input type="checkbox"/> mood swings                 | <input type="checkbox"/> sores, skin/mouth     |
| <input checked="" type="checkbox"/> disorientation       | <input checked="" type="checkbox"/> hives                   | <input type="checkbox"/> muscle pain/weakness        | <input type="checkbox"/> swallowing difficulty |
| <input checked="" type="checkbox"/> dizziness            | <input type="checkbox"/> hypertension                       | <input checked="" type="checkbox"/> nasal congestion | <input type="checkbox"/> tinnitus              |
| <input type="checkbox"/> other: _____                    |   |  |  |

Please act on behalf of the millions of people who have suffered physical illness and injury resulting from fragrance exposure at work, at school and in social settings. These toxic chemicals act as powerful barriers to people disabled by asthma and chemical sensitivities. Toxic chemicals in fragrances have already ruined countless lives. Thank you.

Sincerely,

Gail Vareille  
your name

C422

304 E. 65 ST, New York, N.Y. 10021  
address, city/st/zip

Newsletters and everyone who feels people have a right to know, please copy, share, tell your friends and WRITE the FDA ... today!

Sciences, called for more clinical tests of humans exposed to pesticides and other hormonally active environmental chemicals. Said one panelist, Dr. Ana M. Soto, "few studies have probed for effects in humans. . . . Most people face coincident exposures to several hormone mimics—such as nonylphenols, phthalates, and PCBs." Her own studies indicate that the effects can be "at least additive"—from the Aug. 14 Wall Street Journal, sent by Karen Truskowski, and the Aug. 14 Science News, sent by Scott Spiegel.

➤ **Small victories:**

(1) **Baxter International**, one of the largest manufacturers of medical supplies, will phase out the use of polyvinyl chloride in its IV bags and tubing; and Kaiser Permanente, the nation's largest nonprofit HMO, will stop using vinyl gloves—from the July Green Guide.

(2) **Unilever Home & Personal Care USA** has been prohibited by the Federal Trade Commission from claiming that its Vaseline Brand Intensive Care Antibacterial Hand Lotion "stops germs longer than washing alone. No marketing claims will wash without adequate substantiation"—from the Sept. 16 Chicago Tribune. [Hooray!]

(3) In what is possibly a large victory, about 600 NGOs (nongovernmental organizations) defeated an attempt by 29 of the world's richest nations, including the US, to write a treaty on foreign investment (MAI, the Multilateral Agreement on Investment). The NGOs charged that the proposed global treaty, seemingly a technical exercise, would override local and

national laws on the environment and the rights of women and minorities—from the July 5 Chicago Tribune.

(4) "The **Code Alimentarius Commission**, the UN Food Safety Agency representing 101 nations worldwide, has ruled unanimously in favor of the 1993 European moratorium on Monsanto's genetically engineered hormonal milk (rBGH). This unexpected ruling, revealingly greeted by the US press with deafening silence, is a powerful blow against US global trade policies which are strongly influenced by powerful multinational corporations, such as Monsanto. . . . [This] ruling represents the first large-scale defeat of genetically modified foods on unarguable scientific grounds, apart from ethical and ideological concerns"—from an Aug. 18 press release by Samuel S. Epstein, MD, Professor of Environmental Medicine, University of Illinois at Chicago, e-mailed by Anne Jackson.

➤ **On genetically modified food:** In the last two months, the US mainstream press has begun to tackle this topic. Consider the following headlines: "Altered food might mutate trade" (July 14 USA Today); "USDA beefs up biotech regulatory process" (July 19 Chemical & Engineering News); "The Curse of Frankenfood" (four pages in the July 26 U.S. News & World Report); "Bugs May Develop Resistance to New Crops Faster Than Expected" (Aug. 5 Wall Street Journal); "Reflecting Europe's view, British militants destroy altered crops" (Aug. 5 Chicago Tribune); "Aversion to gene-altered crops spreading to international buyers" (Aug. 29 Denver Rocky Mountain News); and "Seeds of Change" (six pages in the September Consumer Reports). Opposition is growing!

MCS: Health & Environment  
(a support group for the chemically sensitive)  
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GAIL VAREILLES  
304 E 65TH ST APT 15A  
NEW YORK NY 10021 US  
R

An "R" on your label  
means please renew now.